

If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

In the present requirement, it has been alleged that the groups of claims are distinct, but the requirements for establishing “distinctness” have not been met. There has been no showing that the process of the claims can be used to make a different product, or that the claimed crystalline cetirizine monohydrochloride can be made by a different process. The cited Duchene et al. document (US 6,255,487 B1) in column 19 appears to show only a preparation of cetirizine in its free form, not a hydrochloride salt as was asserted in the Office Action, and therefore is not at all relevant to the restriction determination. Applicants submit that, even if the cited document described a preparation of a hydrochloride salt, it would not be relevant for restriction purposes unless it described preparing the particular claimed hydrochloride salt.

Further, the requirement that the claim groups would be able to support separate patents has not even been addressed. It is stated in M.P.E.P. § 802.01:

Related inventions are distinct if the inventions *as claimed* are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER ...

Failure to address this requirement renders the restriction requirement improper.

All of the claims of this application are directed to a crystalline form of the drug compound cetirizine monohydrochloride. For this reason, a search strategy for any one of the groups of claims would also be the appropriate strategy for any other group; only a single chemical compound is involved. A search relating to the claimed compound would necessarily encompass documents relating to processes for its preparation and all other technology relating to the compound. For this reason, no undue burden will be involved in searching and examining all of the pending claims together.

In view of this discussion, withdrawal of the restriction requirement and examination of all pending claims is requested. However, if the requirement is to be maintained, Applicants provisionally select Group I, including the claims 1-21 and 32 for initial examination.

If any further issues remain to be addressed in connection with this submission, please contact the undersigned for resolution of the issues.

Respectfully submitted,

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January 8, 2007

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